



auxogyn

Eeva™ Petri Dish, K103028

**Section 5: 510(k) Summary**

AUG 11 2011

**Device Information:**

Category	Comments
Sponsor:	Auxogyn, Inc. 1490 O'Brien Drive, Suite A Menlo Park, CA 94025 Tel: 650-641-2429
Correspondent Contact Information:	Robert Newman VP of Regulatory Affairs Auxogyn, Inc. 1490 O'Brien Drive, Suite A Menlo Park, CA 94025 Tel: 650-641-2429
Device Common Name:	IVF Tissue Culture Dish
Device Classification Number:	21 CFR 884.6160 Assisted Reproduction Labware
Device Classification & Product Code:	Class II MQK
Device Proprietary Name:	Eeva™ Petri Dish

**Predicate Device Information:**

Predicate Device:	SunIVF Embryo Corral Dish
Predicate Device Manufacturer:	<GenX> International, Inc.
Predicate Device Common Name:	IVF Tissue Culture Dish
Predicate Device Premarket Notification #	K993881
Predicate Device Classification:	21 CFR 884.6160 Assisted Reproduction Labware
Predicate Device Classification & Product Code:	Class II MQK

**b. Date Summary Prepared**

August 3rd, 2011

**c. Description of Device**

The Eeva™ Petri Dish is 39mm in diameter with a lid and consists of a large center well containing 16 or 25 micro-wells. The Eeva Petri dish also contains three smaller outer rings, approximately 7mm in diameter each, which are intended to hold media drops for rinsing the oocytes or embryos.

The Eeva™ Petri Dish is constructed of polystyrene and is non-pyrogenic and non-embryotoxic.



**d. Indication for Use**

The Eeva™ Petri Dish is intended to be used to hold human oocytes and embryos during handling and culture.

**e. Comparison to Predicate Device**

The Eeva™ Petri Dish is substantially equivalent in intended use, Indication for Use, materials and design to the predicate device, the SunIVF Embryo Corral Dish, originally cleared as the <genX> dish (K993881).

Both devices are used to culture embryos during IVF procedures. Both devices are constructed of 100% virgin polystyrene. Both devices allow for the segregation of embryos while immersed in the same drop of culture media. Both devices are non-pyrogenic and non-embryotoxic.

Both devices are single use only and are gamma irradiation sterilized.

Auxogyn, Inc. concludes that the devices are substantially equivalent.

**f. Summary of Supporting Data**

The Eeva™ Petri Dishes are non-pyrogenic as tested by LAL and non-embryotoxic as tested by 1-Cell Mouse Embryo Assay (MEA), with  $\geq 80\%$  of embryos developed to expanded blastocyst stage within 96 hours.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Robert Newman  
Vice-President, Regulatory Affairs  
Auxogyn, Inc.  
1490 O'Brien Drive, Suite A  
MENLO PARK CA 94025

AUG 11 2011

Re: K103028  
Trade Name: Eeva™ Petri Dish  
Regulation Number: 21 CFR §884.6160  
Regulation Name: Assisted reproduction labware  
Regulatory Class: II  
Product Code: MQK  
Dated: August 3, 2011  
Received: August 5, 2011

Dear Mr. Newman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

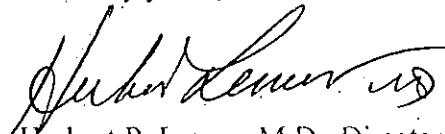
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



#### Section 4: Indications for Use Statement

510(k) Number (if known): K103028

Device Name: Eeva™ Petri Dish

Indications For Use:


The Eeva™ Petri Dish is intended to be used to hold human oocytes and embryos during handling and culture.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K103028